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CONFIRMATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. FILING DATE APPLICATION NO. 12/07/1998 MIRI SEIBERG JBP438 5255 09/206,249 07/15/2003 PHILIP S. JOHNSON, ESQ. **EXAMINER** JOHNSON & JOHNSON MELLER, MICHAEL V ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 ART UNIT PAPER NUMBER 1654 DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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• •	Application No.	Applicant(s)
Office Action Summary	09/206,249	SEIBERG ET AL.
	Examiner	Art Unit
	Michael V. Meller	1654
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status		
1) Responsive to communication(s) filed on 23 June 2003.		
2a) This action is <b>FINAL</b> . 2b) This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims  A) Claim(a) 24 28 26 28 40 44 47 and 58 is/are p	anding in the application	
4) Claim(s) 24,28-36,38,40,44-47 and 58 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
5)		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9)☐ The specification is objected to by the Examiner.		
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12)☐ The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>		
Attachment(s)		
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>	5) Notice of Inform	ary (PTO-413) Paper No(s) al Patent Application (PTO-152)

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# **DETAILED ACTION**

#### Election/Restrictions

The elections of species of record is maintained for the reasons of record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

## Claim Rejections - 35 USC § 102

Claims 24, 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Limtrakul et al.

Applicant argues that Limtrakul does not apply the same composition as applicants because applicant argues that the soybean milk of Limtrakul must have had the STI inactivated because otherwise it would not have been suitable for the mouse to ingest.

Nowhere in Limtrakul do they say that the STI in the soybean milk was inactivated. Thus, the same composition as applicants was given to the mice in Limtrakul.

Thus, the reference clearly teaches administration of the composition to a mammalian cell.

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Claims 24, 28-36, 38, 40, 44-47 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Kosaka.

Applicant argues that Kosaka teaches use of papain and citric acid. While this may be true, Kosaka also teaches administering soybean milk. Applicant argues that citric acid is not required by the claims, but the claims do not exclude citric acid so applicant is incorrect in their statement. The claims do read on using citric acid. Applicant's claims have <u>not</u> excluded the use of citric acid.

Claims 24, 28-36, 38, 40, 44-47 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 62036304 (applicant notes this reference as Katsumi).

JP teaches a composition containing soybean milk which is applied to the skin. Whether or not the soybean milk is heated it will still have the STI in it. Applicant's comments make no sense since the STI is still in the soybean milk. If the STI is not there, then where did it go?

Without more, the claims are clearly anticipated by the reference.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 24, 28-36, 38, 40, 44-47 and 58 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/110,409 which has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application.

Applicant's comments concerning this rejection make no sense. Applicant even admits that the inventive entities are one and the same as the instant application and that of 09/110,409. Thus, it is not understood what applicant is arguing.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appro-priate showing under 37 CFR 1.131.

This rejection may <u>not</u> be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

## Claim Rejections - 35 USC § 103

Claims 24, 28-36, 38, 40, 44-47, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limtrakul et al. taken with Kosaka or JP 62036304.

The above discussions also apply to this rejection.

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## **Double Patenting**

Claims 24, 28-36, 38, 40, 44-47 and 58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent No. 09/110,409. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims have not in fact been patented.

Without the terminal disclaimer, this rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Michael V. Meller Primary Examiner Art Unit 1654

MVMJuly 11, 2003

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